REMARKS/ARGUMENTS

The present Amendment and Response comprises Applicant's reply to the Examiner's July 7, 2009 Final Office Action. Claims 1, 6, 13, 15, 16, and 23 are currently amended and Claims 2-4, 7-12, 14, 17-21, and 24-25 are cancelled. Accordingly, Claims 1, 5-6, 13, 15-16, and 22-23 are now pending in view of the above amendments.

Applicant believes that no new matter has been added with regard to the claim amendments provided herein. Applicant does not donate or disclaim any claims or subject matter with the claim amendments made herein, and the Applicant expressly reserves the right to prosecute the original claims or any unclaimed subject matter in one or more future filed continuing applications.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, the Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding. Also, Applicant's arguments related to each cited reference are not an admission that the cited references are, in fact, prior art.

I. Advisory Action Requested

As Applicant has filed a response within two months of the July 7, 2009 notification date of the Final Office Action, Applicant respectfully requests the Examiner to issue an Advisory Action.

II. Rejection Under 35 U.S.C. § 101

The Examiner rejected Claims 24-25 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicant has cancelled Claims 24 and 25, thus this rejection is now moot.

It is further noted that Applicant has amended Claims 1, 6, 13, 15, 16, and 23 to clarify antecedent basis issues and/or to clarify the wording of the claims. Applicant believes that no new matter has been added by such amendments.

III. PRIOR ART REJECTIONS

A. Rejection Under 35 U.S.C. § 102(e)

The Examiner rejected Claims 1, 4, 6, 7, 12, 13, 16, 17, 18, and 22-25 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2005/0065597 to Lansac ("Lansac").

As an initial matter, Lansac was published March 24, 2005 (prior art date). The present application was filed on March 19, 2005, and claimed priority to PCT Application No. PCT/KR2004/00694, which was filed on March 26, 2004, and published in English on October 7, 2004. Accordingly, the earliest priority date for the present application is March 26, 2004, wherein such filing date pre-dates Lansac. Thus, Applicant respectfully requests that the rejection based on Lansac be withdrawn.

The Examiner rejected Claims 1, 5, 7, 10, 13, 15, 18, 24, and 25 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Publication No. 2007/00016290 to Duran ("Duran"). The Examiner stated Duran discloses a discontinuous stabilizing device for the aortic annulus and a continuous stabilizing device for the sinotubular junction and a method of implanting the devices at such locations. The Examiner also rejected Claims 1, 4, 7, 22, and 24-25 under 35 USC 102(e) as anticipated by U.S. Patent No. 6,511,506 Chevillon et al ("Chevillon"). The Examiner stated Chevillon disclosed a discontinuous device capable of use at an aortic annulus and a continuous device capable of placement at a sinotubular junction. The Examiner stated Chevillon's discontinuous device has a thinned area.

It is well recognized that claims are anticipated if, and only if, each and every element, as set forth in the claim is found in a single prior art reference. Vertegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown as a complete detail as contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989). See MPEP § 2131. To constitute anticipation, all material elements of the claim must be found in one prior art source. In re Marshall, 198 U.S.P.Q. 344 (C.C.P.A. 1978). Additionally, the elements of the reference must be arranged as required by the claim. In re Bond, 15 U.S.P.Q. 2d 1566 (Fed. Cir. 1999). As described in detail below, Applicant respectfully submits that the cited references do not teach all the materials elements and do not arrange the elements as required by the rejected claim language.

As amended, Claim 1 now reads:

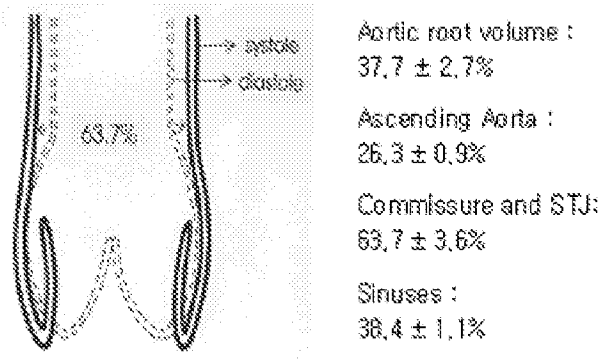
> An apparatus for restoring an aortic valve having an aortic annulus with a diameter, a sinotubular junction with a diameter, and an aortic lumen including a wall and an inside and an outside, the apparatus comprising:
> a) a discontinuous aortic annulus stabilizing device sized and configured to be implanted proximate the aortic annulus of the aortic valve for uniformly stabilizing the diameter of the aortic annulus and adapted to be attached to the

inside and outside of the aortic lumen, wherein the discontinuous aortic annulus stabilizing device and the continuous sinotubular junction stabilizing device are made of a synthetic fiber, and wherein a sewing passage of the inner discontinuous aortic annulus stabilizing device and the inner continuous sinotubular junction stabilizing device are formed thinner than a surrounding area in order to adhere the inner discontinuous aortic annulus stabilizing device and the inner continuous sinotubular junction stabilizing device tightly to the wall of the aortic lumen associated with the aortic valve; and

b) a continuous sinotubular junction stabilizing device sized and configured to be implanted proximate the sinotubular junction of the aortic valve for uniformly stabilizing the diameter of the sinotubular junction from an inside and an outside of the sinotubular junction.

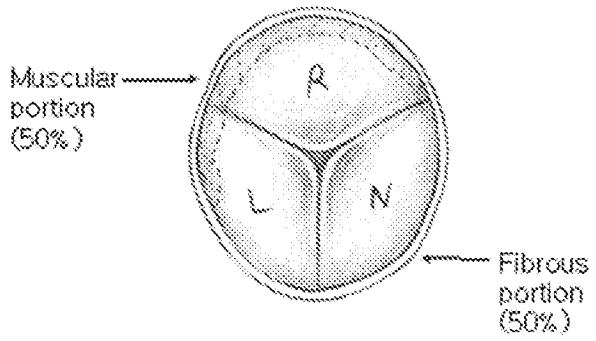
The present invention relates to an apparatus for restoring an aortic valve implanted to the aortic root. During the process of systole, the aortic root volume expands to about 37.7% and the sinotubular junction expands to about 63.7% compared with the process of diastole (Fig. 1, below). The present invention adopts a synthetic fiber, which is reflected in Claim 1 as currently amended. The synthetic fiber allows stabilizing devices to expand up to the uppermost limit of normal human sinotubular junction expansion, but prevents further expansion during the process of systole. The synthetic fiber also allows stabilizing devices to contract sufficiently during the process of diastole.

[Figure 1]

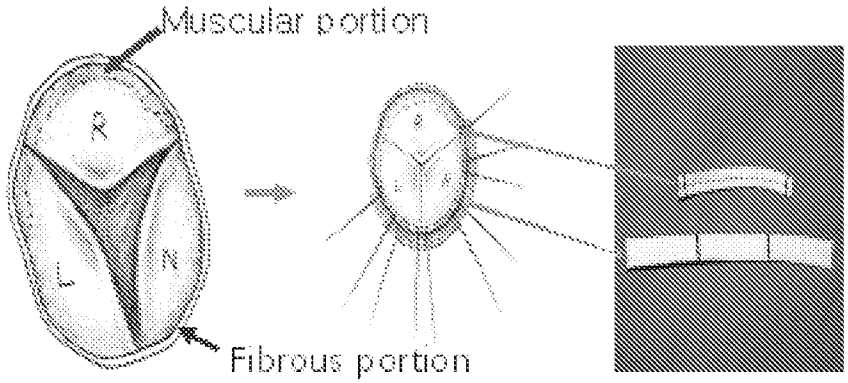


Further, the aortic annulus stabilizing device of the present invention has a discontinuous form that is a band form, not a ring form. Since the aortic annulus consists of a muscular portion and a fibrous portion (Fig. 2, below), the discontinuous aortic annulus stabilizing device is attached only to the fibrous portion so that it stabilizes only the fibrous portion of the aortic annulus and not the muscular portion (Fig. 3, below).

[Figure 2]



[Figure 3]



The present invention also has sewing passages on the inner discontinuous aortic annulus stabilizing device and the inner continuous sinotubular junction stabilizing device, which is thinner than the surrounding part. This thinner part is in direct contact with the tissues in order

to enable tight apposition of the inner discontinuous aortic annulus stabilizing device and the inner continuous sinotubular junction stabilizing device to the tissues.

B. Duran and/or Chevillon Cannot Anticipate the Present Invention

Duran discloses a discontinuous stabilizing device. However the term "discontinuous" as used in Duran means that the outflow orifice of the valve is attached to the outflow circular support only at three points, not through the whole circular support. On the other hand, the term "discontinuous" as used in the present invention means that the device has a band form, not a continuous ring form. Consequently, Duran discloses only continuous (the ring form according to the present invention) stabilizing devices. Therefore, the devices of Duran and the present invention are quite different from each other.

Duran discloses devices to be made of synthetic fiber or a biocompatible material. However, the Applicant has amended Claim 1 to include only "a synthetic fiber" not "or biocompatible material." Duran also discloses only a biocompatible polymer as a component of the membrane that is used for the manufacture of the sigmoid valve, not as a component of supports or stents. Further, the stents and the supports of Duran consist of metal wire, plastic rings, or suture filament. The synthetic fiber of Duran, however, does not disclose a synthetic fiber which expands or contracts according to the rhythmic changes of the cardiac cycle. Duran discloses only one part for the inner supports or stents to fix the sigmoid valve. Therefore, it is quite different from the present invention, which uses both an inner and outer stabilizer together. In addition, the present invention claim a thinner sewing passage on the inner stabilizing devices to make tight apposition to the tissue. This structure is not disclosed by Duran.

Applicant respectfully traverses the rejection based on Chevillon. The Examiner indicates that Chevillon discloses a discontinuous device and a continuous device. However,

Chevillon discloses an outer discontinuous device and an inner continuous device. The outer discontinuous device is used at the upstream and downstream end of the implant separately, but the inner continuous device is connected from the upstream to the downstream end of the implant and the upper part and the lower part is made of metal. In contrast, the present invention claim an inner and an outer discontinuous device implanted in the aortic annulus and a separate inner and an outer continuous device implanted in the sinotubular junction. That is, in the present invention, the discontinuous devices and the continuous devices are physically separated as (a) an inner and (b) an outer device. Due to this structural difference, the implant location is also different. The device of Chevillon can only be used in a blood vessel that has no valve because its inner continuous device is connected from the upstream to the downstream end of the implant. On the other hand, the present invention is used in an aortic annulus and a sinotubular junction, on both sides of the aortic valve. The inner device of Chevillon is continuous. However, in the present invention, both inner and outer devices used in the aortic annulus may be discontinuous to fix only the fibrous portion of the aortic annulus. Moreover, the stabilizing devices of the present invention, unlike Chevillon, are made of a synthetic fiber so as to expand or contract according to the rhythmic changes of the cardiac cycle as discussed above.

Therefore, Applicant believes the present invention is not anticipated by Duran and respectfully requests that the rejection under 35 U.S.C. §102(e) based upon Duran be withdrawn. Further, Applicant believes the present invention is distinguishable from Chevillon and thus, not anticipated. Applicant respectfully requests that the rejection under 35 U.S.C. §102(e) based upon Chevillon also be withdrawn.

Notwithstanding the above, because Duran and Chevillon are only citable under 35 U.S.C. § 102(e), Applicant does not admit that Duran or Chevillon are in fact prior art to the

claimed invention. The Applicant also reserves the right to swear behind Duran and/or Chevillon, if necessary, to remove one or both references.

CONCLUSION

In view of the foregoing, Applicant believes the claims as amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Applicant believes no fees are due for this submission. However, please credit any over payment or debit any under payment to Deposit Account No. 08-2665.

Respectfully submitted,

HOLME ROBERTS & OWEN LLP

/Paul S. Cha/

Paul S. Cha
Registration No. 54,022
Customer No. 23337
Phone: (303) 861-7000
Facsimile: (303) 866-0200

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